

REMARKS

Claims 1-22 remain pending in the present application. Claims 1-10 stand withdrawn from consideration pursuant to a restriction requirement issued by the Examiner. Claims 11-22 stand rejected on various grounds, discussed below.

Applicant requests entry of the amendment to claim 11 to address the rejection under U.S.C. §112, first paragraph, as set forth in the outstanding Office Action. Basis for the amendment can be found at page 3, lines 7-9 of the specification, and generally throughout the specification.

Rejection under 35 U.S.C. §112, first paragraph

Claims 11-22 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicant traverses this basis for rejection and respectfully requests reconsideration and withdrawal thereof, in view of the accompanying amendment.

Applicant submits that the amendment, if entered, should overcome the rejection.

Rejections under 35 U.S.C. §103(a)

Claims 11-14 and 21-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Gonzales-Ryan et al., in view of Annas.

Claims 11-14 and 17-20 stand rejected under 35 U.S.C. §103(a) as being obvious over Blood Plasma Pooling in view of Annas.

Claims 11-14, 17, 18 and 21-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Kline and/or Wolf, Jr., in view of Annas.

Claims 11-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Boyse in view of Annas.

Applicant traverses these bases for rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant reiterates his comments in traverse of the above-stated rejections, essentially as set forth in his prior response filed 22 December 2003. As is recognized by the plethora of references cited by the Examiner, none of the individual references discloses or even suggests dividing of the collected sample of umbilical cord blood containing stem cells into at least two portions and selling or donating one portion and using the proceeds of the sale or donation to defray the cost of storing the other portion, as claimed herein.

Applicant respectfully submits that the complex combination of reference teachings and the rejections based thereon are clearly an impermissible hindsight reconstruction of the present invention, derived not from the cited prior art references, but from a reading of the present specification and claims. There is absolutely nothing in the cited references which would motivate the skilled artisan to combine the reference teachings in the manner that the Examiner has proposed.

At page 7 of the outstanding Office Action, the Examiner states:

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to sell cord blood in the event that the storage costs can not be paid for its well known value, as disclosed by Annas. It would have been further obvious to one of ordinary skill in the art to maintain at least a portion of the blood, as storage of the cord blood is the purpose for needing the monetary gain. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Annas to sell a portion of cord blood with a reasonable expectation for successfully paying for storing another portion.

These statements by the Examiner are merely a series of legal conclusions, without any specific indication of what within the reference teachings themselves would have provided motivation to a skilled artisan to combine and/or modify those teachings. As such, Applicant submits that the Examiner's legal conclusions of obviousness are unfounded.

Again at page 7 of the Office Action, the Examiner states:

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. (Citation omitted).

Applicant takes issue, not with what knowledge was derived from the references, nor that within the level of ordinary skill in the art, but with the improper derivation of the motivation to combine the reference teachings.

The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Further, it is well-established in the patent law that

[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Again, Applicant asserts that the skilled artisan could not derive a motivation to combine the cited prior art references in the manner of the present invention, from within the reference teachings. Any such combination of reference teachings has been impermissibly derived from the present application, and not from the prior art.

However, even if combined in the manner proposed by the Examiner, the references fail to disclose an important element of the claims: That of dividing the umbilical cord blood containing stem cells into at least two portions (claim 11). None of the reference, either alone or in combination, disclose dividing umbilical cord blood containing stem cells into at least two portions. Blood Plasma Pooling discloses first fractionating blood into a plasma portion and a cellular containing portion, but fails to disclose dividing whole blood into portions, each of which remains whole blood.

In contrast, according to claim 11, after the dividing step, one portion of umbilical cord blood is stored and one portion of umbilical cord blood is sold. Claim 11 does not recite fractionating the umbilical cord blood into a plasma portion and a cellular containing portion, nor selling plasma separated from umbilical cord blood.

To establish a *prima facie* case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations. In re Vaeck.


Accordingly, the cited references, even in combination, fail to establish a *prima facie* case of obviousness as to the present claims.

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Withdrawal of the rejections and allowance of the claims is
requested.

Respectfully submitted



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